United States District Court
District of Massachusetts

William Ortega,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Civil Action No. 22-10511-NMG**
	)	
Merck & Co., Inc., Merck Sharp & Dohme Corp., Organon & Co. and Organon, LLC,	)	
	)	
Defendants.	)	
	)	

MEMORANDUM & ORDER

Plaintiff William Ortega ("Ortega" or "plaintiff") brings this personal injury action against Merck & Co, Inc. and Merck Sharp & Dohme Corp. ("Merck defendants" or "Merck") and Organon & Co. and Organon, LLC ("Organon defendants" or "Organon") (all collectively referred to as "defendants").

The case arises from allegations that plaintiff's neuropsychiatric injuries were caused by Singulair, a pharmaceutical product manufactured by Merck. Plaintiff, who was prescribed Singulair, asserts that Merck knew or should have known of the risks of those injuries prior to selling the product. He brings claims for design defect, failure to warn, negligence, misrepresentation and breach of express warranty.

Pending before the Court is defendants' motion to dismiss the design defect claims.

I. Background

A. Singulair

Singulair, which contains the active ingredient montelukast, was patented by Merck in 1996 and received approval for use from the Food and Drug Administration ("FDA") in 1998. Merck was the exclusive manufacturer, distributor and seller of Singulair from 1998 to mid-2012, when its patent expired. At that point, other companies were approved to market generic montelukast in the United States. Singulair is indicated for (1) prophylactic and chronic treatment of asthma, (2) acute prevention of exercise-induced bronchoconstriction ("EIB") and (3) relief of symptoms of allergic rhinitis.

The complaint alleges that montelukast has been tested extensively and many of those studies demonstrate a correlation between Singulair usage and the development of neuropsychiatric events. As set forth in the complaint, montelukast crosses the blood-brain-barrier, which is a semi-permeable membrane of cells that protects the brain and the central nervous system from pathogens. Very few drugs are able to pass the blood-brain-barrier to impact the central nervous system. Because montelukast does so, it purportedly exerts a systemic effect

upon the central nervous system that results in, among other things, adverse neuropsychiatric events.

When Singulair was first introduced to the market in 1998, the label contained no warnings regarding neuropsychiatric events. According to the complaint, Merck has since "belatedly added grossly insufficient warnings" to the product label. In March, 2020, the FDA required Merck to add a "Black Box Warning," the strongest kind of warning, to the Singulair label to warn that "serious neuropsychiatric events have been reported in patients taking Singulair."

B. The Parties

The Merck defendants are New Jersey corporations that manufacture and sell pharmaceutical drugs. Their subsidiaries, the Organon defendants, are headquartered in Delaware. According to the complaint, Merck has maintained control of the brand name "Singulair" until at least 2020 and perhaps even through the filing date of the complaint. Plaintiff alleges that he believes Merck "spun off" Singulair to its subsidiary Organon after the FDA ordered Merck to add the Black Box Warning to the label.

The complaint asserts that Merck manufactured, marketed and sold millions of Singulair pills in Massachusetts, including those that plaintiff allegedly ingested. Moreover, the

defendants allegedly engaged in an extensive campaign to educate Massachusetts physicians about the purported benefits of Singulair and misrepresented the safety of the drug. The defendants also apparently engaged in direct-to-consumer advertising in Massachusetts, including in print magazines and television commercials.

Plaintiff Ortega resides in Hampden County, Massachusetts and was prescribed Singulair from 2000 to 2009. As alleged in the complaint, his prescriptions were filled with branded generic Singulair. Plaintiff contends he used Singulair as prescribed and, as a direct and proximate result of ingesting Singulair, suffered neuropsychiatric injuries including depression and social anxiety.

C. Procedural History

Plaintiff initiated this suit in the Massachusetts Superior Court for Middlesex County in March, 2022. Defendants removed the case to this Court based upon diversity jurisdiction and timely moved to dismiss plaintiff's claims.

Defendants also filed a District of Massachusetts Local Rule 40.1(g)(5)(B) certification designating the present case as related to seven other pending cases in this district. Defendants asserted that all plaintiffs in those cases sought damages for neuropsychiatric injuries allegedly caused by

branded or generic Singulair and, other than the identities of the plaintiffs, the dates of usage and specific kinds of neuropsychiatric injures, the allegations in the complaints were essentially the same. Defendants contended that they will assert common legal defenses in all of the cases.

The judge assigned to the case, United States District Judge Richard G. Stearns, ruled, however, that the factual disparities among the individual plaintiffs' cases——including: (1) broad differences in the time periods and frequencies during which plaintiffs were prescribed Singulair or its generic (between 2000 and 2020), (2) the intervening changes in the contents of the published warnings during that same time span, and (3) the predictable differences with respect to individual damages and causation——fail the "related civil case" standard set forth in the District of Massachusetts Local Rule 40.1. Judge Stearns concluded there were no circumstances under which a joint trial of the cases would be practicable.

Accordingly, Judge Stearns returned all but the first-filed case to the Court Clerk for reassignment. The case at bar, as well as Barnes v. Merck & Co., Inc., 22-10496, were assigned to this session.

II. Motion to Dismiss

A. Legal Standard

To survive a motion under Fed. R. Civ. P. 12(b)(6), the subject pleading must contain sufficient factual matter to state a claim for relief that is actionable as a matter of law and "plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). A claim is facially plausible if, after accepting as true all non-conclusory factual allegations, the court can draw the reasonable inference that the defendant is liable for the misconduct alleged. Ocasio-Hernandez v. Fortuno-Burset, 640 F.3d 1, 12 (1st Cir. 2011).

When rendering that determination, a court may not look beyond the facts alleged in the complaint, documents incorporated by reference therein and facts susceptible to judicial notice. Haley v. City of Boston, 657 F.3d 39, 46 (1st Cir. 2011). A court also may not disregard properly pled factual allegations even if actual proof of those facts is improbable. Ocasio-Hernandez, 640 F.3d at 12. Rather, the necessary inquiry focuses on the reasonableness of the inference of liability that the plaintiff is asking the court to draw. Id. at 13. The assessment is holistic:

> the complaint should be read as a whole, not parsed piece by piece to determine whether each allegation, in isolation, is plausible[.]

Hernandez-Cuevas v. Taylor, 723 F.3d 91, 103 (1st Cir. 2013), quoting Ocasio-Hernandez, 640 F.3d at 14.

B. Application

Defendants move to dismiss plaintiff's design defect claims on two grounds: (1) they are barred under comment k of the Restatement (Second) of Torts, § 402A and (2) they are preempted by federal precedent. In Count I, a breach of warranty/design defect claim, plaintiff asserts that Singulair was "defective, unreasonably dangerous, and unsafe for its intended purpose," and thus contends that defendants are "strictly liable for the damages caused" to him. Then, in Count III, a negligence claim, plaintiff argues that defendants "[f]ail[ed] to use reasonable and prudent care in the design" of Singulair.

As courts in this district have previously held in Singulair-related cases, plaintiff's design defect claims are preempted by federal law. See Baiona v. Merck & Co. et al., No. 22-cv-10474-RGS, ECF No. 27 (D. Mass. June 2, 2022) (dismissing Singulair design defect claims in a nearly identical complaint).

Pursuant to 21 C.F.R. § 314.70(b), "major changes" to a drug product must be submitted to the FDA for approval prior to the distribution of the product incorporating the change. Thus,

a pharmaceutical company cannot unilaterally implement "major changes" to the chemical formulation of a medication that the FDA has previously approved. Gustavsen v. Alcon Labs., Inc., 903 F.3d 1, 10 (1st Cir. 2018) ("Major changes require approval from the FDA prior to implementation, while moderate and minor changes do not.").

In his complaint, Ortega suggests that safer, feasible alternative designs for Singulair were available, including modifying montelukast itself or modifying Singulair without modifying montelukast, both with the goal of rendering it less likely to cross the blood-brain-barrier and contribute to adverse neuropsychiatric events. Because such modifications are "major changes" to the formation of Singulair pursuant to 21 C.F.R. § 314.70(b)(2), federal law preempts this cause of action. Defendants cannot lawfully implement such a change without prior FDA approval. See id.

Thus, the Court will dismiss Count I (design defect) and Count III (negligence) insofar as Count III alleges negligent design.

Plaintiff also requested in his opposition brief leave to amend his complaint if the Court allows defendants' motion to dismiss as to any of his claims. In this case, that request will be denied. Although Fed. R. Civ. P. 15(a)(2) encourages

the Court to "freely give leave when justice so requires," no prospective amendment to Ortega's complaint could alter the fact that any claims against defendants concerning the design of Singulair are preempted by federal law.

ORDER

For the foregoing reasons, defendants' motion to dismiss Count I (design defect) and Count III (negligence), insofar as Count III alleges negligent design, (Docket No. 13) is **ALLOWED.**

Plaintiff's request to amend his complaint (treated as a motion) is **DENIED.**

So ordered.

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated January 4, 2023